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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

APTALIS PHARMA US INC., and APTALIS PHARMA CANADA INC., Plaintiffs, v. SANDOZ INC., Defendant.	Honorable Mary L. Cooper, U.S.D.J. Civil Action No. 13 CV 4290 (MLC)(LHG) **DECLARATION OF DR. JONATHAN W. STEED IN SUPPORT OF SANDOZ'S OPENING CLAIM CONSTRUCTION BRIEF AND MYLAN PHARMACEUTICALS INC. AND MYLAN, INC.'S OPENING CLAIM CONSTRUCTION BRIEF**
APTALIS PHARMA US INC. and APTALIS PHARMA CANADA INC., Plaintiffs, v. MYLAN PHARMACEUTICALS INC. and MYLAN, INC., Defendants.	Honorable Mary L. Cooper, U.S.D.J. Civil Action No. 13 CV 4158 (MLC)(LHG)

DR. JONATHAN W. STEED, of full age, hereby declares as follows:

I. Introduction

1. I, Jonathan W. Steed, have personal knowledge of the matters stated herein and, if called upon to testify as to those matters, I can competently do so.

2. I have been asked to provide my opinion regarding the meaning of certain claim terms of U.S. Patent Nos. 7,541,384 ("the '384 patent"), 8,217,083 ("the '083 patent"), and 8,436,051 ("the '051 patent") (collectively, "the Asserted patents"). Those terms are as follows:

Claim Term	Claim(s) Reciting Term
• "The [oily or] fatty base has an ascending melting point [ranging] from [*x*] to [y]° C"	• Asserted Claims 3, 4 and 24, and 25 of the '051 patent • Asserted Claims 3 and 4 of the '083 patent • Asserted Claims 4 and 5 of the '384 patent
• "the mesalamine [particles] [has/have] […] a tap density ranging from about 600 to about 800 g/L (as measured by USP <616>)"	• Asserted Claim 1 of the '384 patent • Asserted Claims 1 and 14 of the '083 patent • Asserted Claims 1, 15, 36 and 42-43 of the '051 patent
"the suppository releases … mesalamine … of dissolution as measured with USP Apparatus #2 at 40°C., a paddle rotation speed of 125 rpm, and 3 sinker turns in 0.2 M phosphate buffer at a pH of 7.5"	• Asserted Claims 1 and 10-12 of the '384 patent • Asserted Claims 1, 8-10, 14 and 17 of the '083 patent • Asserted Claims 1, 9-11, 15, 18, 19, 30, 31, 33, 35, 36, 42 and 43 of the '051 patent
• "[the suppository] releases at least [x%] by weight of the mesalamine within [y hours/minutes] of dissolution"	• Asserted Claims 1, 10, 11 and 12 of the '384 patent; • Asserted Claim 10 of the '083 patent; • Asserted Claims 11 and 30 of the '051 patent
• "[the suppository] releases at least about [x%] by weight of the mesalamine within [y hour(s)] of dissolution"	• Asserted Claims 1, 8, 9, 14, 17 of the '083 patent; • Asserted Claims 1, 9, 10, 15, 18, 19, 36, 42, 43 of the '051 patent
• "[the suppository] releases between [x%] and [y%] (w/w) of the mesalamine after [z minutes] of dissolution"	• Asserted Claims 33 and 35 of the '051 patent
• "[the suppository] releases at least [x%] (w/w) of the mesalamine after [y minutes] of dissolution"	• Asserted Claims 31 and 33 of the '051 patent

• " the mesalamine particles have a surface area of from about 0.1 m^2/g to about 2.8 m^2/g"	• Asserted Claims 19, 33, 36 and 42-43 of the '051 patent
• " the mesalamine particles have a surface area of from about 0.1 m^2/g to about 1.3 m^2/g"	• Asserted Claim 20 of the '051 patent
• " the surface area of the mesalamine particles ranges from about 0.1 m^2/g to about 1.3 m^2/g"	• Asserted Claim 37 of the '051 patent
• " the surface area of the mesalamine particles ranges from about 1.3 m^2/g to about 2.8 m^2/g"	• Asserted Claim 34 of the '051 patent

3. These terms generally require the measurement of certain physical properties. As explained below, my opinion is that the asserted patents do not teach a person of ordinary skill how to take the measurements to determine whether the claimed properties are present. Moreover, differences in the method for measuring these properties would result in significant and meaningful differences including whether a product meets a limitation. Thus, in my opinion, a person of ordinary skill in the art would find these terms ambiguous.

4. I have also been asked by Sandoz to provide my opinion regarding the proposed constructions of the following claim terms, which are contained in the document entitled "Plaintiffs Aptalis Pharma US Inc. and Aptalis Pharma Canada Inc.'s Identification of Evidence Under Local Patent Rule 4.2(c)" (the "Aptalis Disclosures")[1]:

Claim Term	Claims Reciting Term	Proposed Construction in the Aptalis Disclosures
• "the drug load ranges from about 39 to about 45%"	• Asserted Claim 8 of the '384 patent • Asserted Claim 6 of the '083 patent	• the drug load ranges from approximately 39% to approximately 45%"

[1] I have reviewed the Aptalis disclosures filed in both the *Aptalis v. Sandoz* case and in the *Aptalis v. Mylan* cases.

	• Asserted Claims 7 and 28 of the ’051 patent	
• “the drug load ranges from about 41 to about 43%”	• Asserted Claim 9 of the ’384 patent • Asserted Claim 7 of the ’083 patent • Asserted Claims 8 and 29 of the ’051 patent	• the drug load ranges from approximately 41% to approximately 43%”

5. As is further explained in detail below, my opinion is that these proposed constructions create significant ambiguity for one of ordinary skill seeking to determine whether the drug load of a suppository is within the claimed ranges.

II. My Background

6. I am Professor of Chemistry at Durham University in the United Kingdom.

7. I obtained my B.Sc. First Class Honors degree and Ph.D. in Chemistry at University College London, working on chemistry related to inorganic drugs and on new synthesis methodologies. I graduated in 1993, winning the *Ramsay Medal* for my Ph.D. work.

8. Between 1993 and 1995, I was a NATO postdoctoral fellow at the University of Alabama and University of Missouri. In 1995, I was appointed as a Lecturer at Kings College London.

9. In 2004, I moved to Durham University where I became full Professor of Chemistry in 2007.

10. I have been awarded a number of national honours for my research into molecular solids, notably the Royal Society of Chemistry *Meldola Medal* (1998) the Royal Society of Chemistry *Bob Hay Lectureship* (2008) and the national *Corday-Morgan Prize* (2010).

11. I am a co-author of the textbooks *Supramolecular Chemistry* (2000 & 2009) and *Core Concepts in Supramolecular Chemistry and Nanochemistry* (2007), and have published over 300 research papers in prestigious, peer-reviewed international journals. I have co-edited the

Encyclopedia of Supramolecular Chemistry (2004), *Organic Nanostructures* (2008) and the eight-volume *Supramolecular Chemistry from Molecules to Nanomaterials* (2012). I was an Associate Editor of *New Journal of Chemistry* from 2001 – 2009 and am currently Associate Editor for the RSC flagship journal *Chemical Communications*. I am a member of a number of editorial and advisory boards including journals focusing on organic solids, crystallization and crystal structure. My published work has been cited over 10,000 times. A complete list of my publications, honours and awards is included in my *curriculum vitae*, a copy of which is attached as Exhibit A.

12. I have also taught numerous courses at the graduate and undergraduate levels, including courses on molecular solids, crystallography and X-ray diffraction.

13. I have developed considerable expertise in solid-state chemistry, and coordination chemistry and intermolecular interactions in solids. I am an expert in the structures and solid state behavior of organic and molecular solids, and in the methods and techniques used to study and characterize them.

14. Based upon my education and experience, I am qualified to express the opinions I provide in this declaration.

III. Materials Reviewed and Brief Background

15. I have reviewed the ’384, ’083, and ’051 patents, and the Aptalis Disclosures. I have also reviewed relevant sections of the United States Pharmacopoeia (“USP”) as of January 1, 2006, and January 1, 2009. Excerpts of the USP are attached hereto as Exhibits B and C, respectively. I have further reviewed literature references which are consistent with my opinions. (Exhibits D, E and F.)

16. By way of brief background, mesalamine is an active pharmaceutical ingredient often used in the treatment of inflammatory bowel diseases and related conditions. Mesalamine may be formulated in a variety of manners for the treatment of these conditions. One such typical

formulation is a suppository, although mesalamine may be employed also in such formulations as tablets, capsules, and enemas. I understand that mesalamine is a commonly-used drug and is generally understood to be quite useful in the treatment of certain medical conditions.

IV. OPINION

17. I understand that my assessment of those claim terms noted above, except those which reference the "surface area" physical property, must be undertaken from the perspective of what would have been known or understood by someone of ordinary skill in the art as of the earliest claimed priority date of the Asserted patents—June 8, 2007 (the filing date of Provisional Application No. 60/943,029 to which the Asserted patents claim priority). Those claim terms concerning "surface area" must be undertaken from the perspective of one of ordinary skill as of December 16, 2009 (the filing date of U.S. Application No. 12/639,645).

18. Based on my experience and analysis of the Asserted Patents, my opinion is that a person of ordinary skill in the relevant art with respect to the Asserted Patents would have at least a doctorate degree in a field related to chemistry or pharmacy and 1-2 years of working or academic experience in the field of pharmaceutical product development and/or molecular materials chemistry or a bachelor's degree in a field related to chemistry or pharmacy and 5-10 years of working or academic experience in the field of pharmaceutical product development and/or molecular materials chemistry.

19. I understand that the claims of a patent must describe with particularity and distinctly claim the subject matter of the invention. I further understand that patent claims must be sufficiently clear that a person of ordinary skill in the relevant art who reads them is able to determine what the claims do and do not cover. I further understand that if a patent claim does not meet this requirement, then it is said to be indefinite and is therefore invalid.

A. The Ascending Melting Point

20. In my opinion, the claim terms identifying an ascending melting point for either the suppository or the oily or fatty base in the suppository are ambiguous to one of ordinary skill.

21. Melting point is the temperature at which a substance passes from the solid to the liquid state. A solid has a melting point. In contrast, a mixture, which is a combination of two or more substances, does not have a well-defined melting point. The phrase "ascending melting point" has no specific meaning or clear reference in the literature. The melting point of fats is particularly difficult to determine because of the chemical and physical nature of fats.

22. There are a number of methods and apparatus that may be employed to determine the melting point of a solid. *See, e.g.*, the USP and the European Pharmacopoeia. A person of ordinary skill in the art would understand and expect that these various methods would produce different results. Indeed, some of these melting point measurements would produce a single melting point and other measurements would produce a range of the melting point.

23. I understand that Aptalis contends that the ascending melting point should include a reference to USP 741. Although USP 741 identifies a number of protocols for measuring a melting point, none of these protocols are described as an "ascending melting point." Indeed, USP 741 identifies two sets of apparatus and five methods for measurement, and none employ that term. I am not aware that Aptalis has identified which of these apparatuses and methods is appropriate to measure the ascending melting point. A person of ordinary skill in the art would not know how to select between these methods and apparatuses, particularly to measure an "ascending melting point."

24. Consistent with my opinion that the term "ascending melting point" has no specific and defined meaning, other literature references indicate that there is confusion over whether the "ascending melting point" is a single point or a range. *See, e.g.*, El-Majri et al., *Formulation and*

Evaluation of Piroxicam Suppositories in International Journal of Drug Delivery 2, 108-112 (2010) (Exhibit D).

25. Focusing on the claims, the claims do not describe a method to determine the ascending melting point of either the oily or fatty base before incorporation into the suppository or after incorporation into the suppository. In addition to the ambiguity created by the failure to identify the apparatus and method for measuring the ascending melting point, a person of ordinary skill in the art would find it very difficult, if not impossible, to determine the ascending melting point range of the fatty base after it has been incorporated into the finished suppository. The presence of the mesalamine in the suppository would obscure the clarity of the melting fat, thus making it impossible to determine with precision the temperature at which the fatty base clarifies. The asserted patents do not address this critical measurement issue, thus leaving ambiguity for one of ordinary skill who reads the patents. Moreover, depending on the amount of mesalamine present in the suppository, the solid powder will interfere with the expansion process of the fat again making the ascending melting point impossible to determine unambiguously.

26. In short, the claim terms providing ascending melting points for the fatty base in the claimed suppository product, in the context of the claims and the patents more broadly, leave substantial ambiguity for one of ordinary skill regarding both how to determine the ascending melting point range and what the true bounds of the melting point range should be.

B. The Tap Density

27. In my opinion, the claim terms which reference the tap density of mesalamine are irretrievably ambiguous to a person of ordinary skill in the art.

28. The term “tap density” is understood within the art to refer to a measurement of the density of a dry powder. The word “tap” refers to the procedure by which the measurement is taken; prior to measurement, the powder is packed or “tapped” down to maximize the density of the

powder. An alternative measurement to the "tap density" is the "freely settled bulk density," which is a measurement of the untapped powder density. The measurement of cooking flour provides a readily understood example. The bulk density of flour is the measure of flour after the flour is run through a sieve. In contrast, the tap density of flour is the measure of flour after the flour is packed or "tapped" into a measuring cup.

29. One of ordinary skill in the art would expect the structure of the particle on which the tap density is to be measured to have a significant effect on the results. Specifically, particles that are more square or more uniform in their size and shape would be expected generally to have a higher tap density than particles that are rounded or less uniform, because the latter types would necessarily have more space between the individual particles after tapping.

30. Although not the only source for information on how to measure tap density, one of ordinary skill in the art could refer to the USP protocol concerning bulk and tapped density, USP 616, in preparing to measure the tap density of a powder. (Ex. B at 2638-2639.) The USP prescribes two separate methods by which to tap the powder to achieve accurate and consistent measurement across samples. (*Id.*) These methods vary according to the number of taps per minute that must be made prior to measuring the density. (*Id.*) They also differ in the "drop height," or the height from which the apparatus containing the powder should be dropped under its own weight to tap down the powder. (*Id.*) The measured tap density of a given powder sample depends in large part on the treatment of the sample pursuant to either of these two methods provided in USP 616. As a general matter, neither method of measuring tap density is generally understood to be preferred. Because the procedure for tapping is critical to consistent measurements of the tap density, a person of ordinary skill in the art would understand that the tap density measurement varies significantly depending on the intensity, duration, and direction of the

tapping. Absent sufficient instruction, the tap density of the mesalamine or mesalamine powder could fall within or outside of the claimed ranges simply as a result of which test is performed.

31. Further, if the tap density were to be measured on the mesalamine after it has been incorporated into the suppository, my opinion is that the patents do not disclose the necessary information to direct one of ordinary skill in how to take the measurement. A skilled artisan would expect that the tap density of the mesalamine after incorporation in the suppository would change. In particular, the mesalamine is incorporated into the base when the base has been heated. The heating process itself would smooth out the surface area of the particles, annealing higher energy irregularities and changing the electrostatic properties of the surface. As noted above, such changes in the surface area, energetics, shape and properties would inevitably affect the tap density measurement. The patents, however, provide no guidance on how to account for the change in the surface area caused by the heating process.

32. For at least these reasons, it is my opinion that the tap density claim terms are insolubly ambiguous.

C. The Surface Area

33. In my opinion, the claim terms in the ’051 patent which prescribe a specific surface area range for the particles of the mesalamine ingredient are irrevocably ambiguous. The term “surface area” is understood within the art to refer to a measurement of the average surface area of a known mass of particles. The surface area of a particle is the area of the object’s faces and curved surfaces. A person of ordinary skill in the art would understand that there are a variety of measurement techniques available to determine surface area and that the results reached are highly dependent on the technique utilized.

34. A person of ordinary skill in the art would be familiar with the literature on surface area measurements. In my opinion, a skilled artisan would also understand that surface area

measurements are notoriously variable based on the measurement utilized. *See, e.g.*, Shin Hong Min, *A Study on Analysis of Particle Size Distribution*, Archives of Pharmacal Research (3(2), 65~74 (1980)) (Exhibit E).

35. In addition, there are variables within each method that a skilled artisan would expect to be provided before any given measurement could be replicated. For instance, in order to perform the gas absorption method referenced above, one must first know how to remove any gases previously absorbed by the particle to be measured. This process of removal is known as "outgassing." The method of outgassing is critical, because the process involves heating the particles for a period of at least several hours. A skilled artisan would know that she must take care to conduct the outgassing in such a manner as not to affect the physical characteristics of the particles. As such, one of ordinary skill would expect the patents to disclose the proper method of outgassing to ensure that the particles were not materially altered.

36. Further, one of ordinary skill would expect that the particular gas to be utilized in the gas absorption method to be identified prior to undertaking the surface area measurement. In particular, appropriate gases to use in the method include nitrogen and krypton. The results of the measurement using each method differ as a result of the varying molecular structures between the two gases. As such, if the gas absorption method were the one chosen, an identification of the gas would be critical to ensuring replicable measurement.

37. Turning to the '051 patent, the '051 patent does not identify any test for the measurement of the surface area of mesalamine either before or after incorporation into the suppository. Thus, in my opinion a person of ordinary skill in the art would not know how to perform an appropriate test on the surface area to produce data suitable for comparison with the patent's claims.

38. I understand that Aptalis wants to include a reference to USP 846. A person of ordinary skill in the art would not have sufficient details from USP 846 to properly measure the surface area of the mesalamine. First, the '051 patent does not identify which of the two USP methods is applicable: the Dynamic Flow Method or the Volumetric Method. These two methods are different and produce different results with different levels of accuracy and precision. For example, the sensitivity limit for the dynamic flow method is around 0.1 m^2/g, which is comparable to the values claimed in the patent.

39. Second, if the person of ordinary skill in the art chooses the Dynamic Flow method, nothing in the '051 tells a person of ordinary skill in the art whether to use nitrogen or krypton. Third, USP 846 does not identify the outgassing procedure to use, the temperature and time or the vacuum or purge gas. In my opinion, all of these parameters would have an impact on the measurement of the surface area for mesalamine. Moreover, in my opinion, these missing parameters would produce significantly different results. As a result, depending on the method chosen, a person of ordinary skill in the art could not determine whether a product meets these limitations.

40. Moreover, if the surface area were measured on the mesalamine after inclusion in the suppository, in my opinion, the claim terms referenced above concerning the surface area of the mesalamine do not provide sufficient information to instruct one of ordinary skill in the art at the time of the invention in how to perform the required measurement. A person of ordinary skill in the art would expect that the process of mixing the mesalamine in the molten base and then hardening the base would change the surface area of the mesalamine particles. The '051 patent provides no guidance to account for the change in surface area caused by the heating and cooling. As such, an ordinary artisan is left without sufficient information to determine if she is utilizing mesalamine with a surface area within the ranges claimed in the patent.

41. In short, the lack of clarity regarding how to measure the surface area of the mesalamine particles creates irresolvable ambiguity.

D. Release And Dissolution

42. In my opinion, the claim term which purports to describe the release of mesalamine from the suppository within a certain time of dissolution leaves significant ambiguity. Indeed, the asserted patents do not explain sufficiently to a person of ordinary skill what is being measured and how and when to measure these properties to achieve accurate and consistent results. Thus, in my opinion, these terms are insolubly ambiguous.

43. As an initial matter, my opinion is that a person of ordinary skill in the art would understand that the claims require the dissolution of the suppository. Further, a person of ordinary skill in the art would understand that "USP Apparatus #2 at 40° C., a paddle rotation speed of 125 rpm, and 3 sinker turns of 0.2 M phosphate buffer at a pH of 7.5" describes some but not all of the conditions under which dissolution occurs. Significantly, a person of ordinary skill in the art would recognize that this list leaves out key parameters, including how the suppository is to be placed in Apparatus #2 and connected to the sinker.

44. A person of ordinary skill in the art would understand that variations in the dissolution can be caused by Apparatus #2 particularly regarding how the suppository is placed in the apparatus. The location of the suppository relative to Apparatus #2 impacts how the dissolving suppository is mixed in the liquid. Suppositories underneath Apparatus #2 will not mix as thoroughly as suppositories to the side of Apparatus #2. This location will substantially impact the dissolution of the suppository and will result in different results by up to 20%. *See, e.g.*, Armenante, Piero and Fernado Muzzio, *In Inherent Method Variability In Dissolution Testing: The Effect of Hydrodynamics in the USP II Apparatus* (Exhibit F). Hence, a person of ordinary skill in the art would need to know where in Apparatus #2 the suppository should be placed.

45. Additionally, one of ordinary skill would expect to be given information on the type of sinker that is to be used to keep the suppository immersed in the dissolution medium. A sinker is typically a piece of metal designed to hold a suppository down and to keep the suppository from floating in the dissolution vessel. Such factors as the size and shape of the sinker could have a significant effect on any resulting dissolution measurement. For example, if a wire sinker were to be utilized, then a skilled artisan would expect to have information on the length and gauge of the wire, as each element can have an effect the rate at which the suppository dissolves. This information is important because the size and shape of the sinker will impact the surface area of the suppository exposed to the phosphate buffer. As more of the suppository is exposed to the phosphate buffer, the suppository would be expected to dissolve more quickly.

46. Additionally, in order to replicate a dissolution rate, a skilled artisan would expect to receive instruction on how the sinker is attached to the suppository. For instance, a sinker that is only lightly attached to the suppository would achieve a dissolution rate which differs from a suppository to which the sinker is more securely attached, as the more secure sinker limits the surface area immediately in touch with the dissolution medium.

47. Another parameter impacting the dissolution would be how the sinker is applied to the suppository. The claims indicate that a sinker with 3 turns should be used, but neither the claims nor the specification describe the type of sinker or how the sinker is secured to the suppository. Specifically, these parameters will have an impact because they will vary the surface area of the suppository exposed to the dissolution medium. The more surface area exposed to the dissolution medium, the faster the suppository would be expected to dissolve. Additionally, a person of ordinary skill in the art would expect that a suppository that is more tightly secured to ensure that it remains submerged would dissolve faster than a suppository which is only loosely connected to the sinker and might escape the sinker and float.

48. A skilled artisan would expect that each of the above parameters, considered separately, could have a potentially significant effect on dissolution. Considered together, then, one of ordinary skill would further expect them to have a greater impact.

49. I understand that Aptalis's response to these missing "dissolution" parameters is to refer to USP 711. A person of ordinary skill in the art would not consider USP 711 to provide the necessary missing information on dissolution. USP 711 expressly states that it applies to "a tablet or capsule dosage form" or "for dosage forms administered orally." (USP 711 at 2673 and 2675.) As a person of ordinary skill in the art, I do not find anything in USP 711 referring to a suppository dosage form. Tablets, capsules, and oral dosage forms are generally water soluble. In my opinion, one of ordinary skill would consider tablets, capsules, and oral dosage forms as different from a suppository, which is an active pharmaceutical ingredient mixed in a non-water soluble fat. Further, this ordinary artisan would recognize that USP 711 is inconsistent with those claims in the asserted patents which include these dissolution parameters insofar as they specify a dissolution medium heated to a different temperature than is specified in the USP. As a result of the inconsistencies, my opinion is that a person of ordinary skill in the art would not look to USP 711 to conduct dissolution testing of a suppository.

50. A person of ordinary skill in the art would expect that all of these missing parameters would impact the dissolution of the suppository, such that it would be necessary for them to be established in order to achieve measurements consistent with those provided in the asserted patents. Thus, without these parameters, my opinion is that a person of ordinary skill in the art would find the dissolution ambiguous.

51. Additionally, despite the details regarding dissolution, neither the claims nor the patent specifications provide any indication of what method should be used to detect the amount of mesalamine that is "released" over time, or of how to avoid interference with the measurement by

the melting fat. In my opinion, it would not be readily clear to one of ordinary skill how to perform these measurements. Indeed, a person of ordinary skill in the art would find no guidance in the Asserted patents for measuring the "release." As a person of ordinary skill in the art, I am aware of multiple ways to measure the amount of mesalamine released in the solution. These methods would include, among others, high pressure liquid chromatography, gas chromatography, infrared absorption, and ultraviolet absorption. A skilled artisan would expect that these methods would produce differences in results, depending for example on the availability of suitable standards, sampling protocol, concentration range being measured, stationary phase, mobile phase and dilution protocol. This difference in results between the methods would be substantial and significant such that a measurement on the same sample might infringe under one test and not infringe under a different test.

52. Further, the asserted patents are ambiguous about how these methods would be performed particularly given the presence of the melted fat in the dissolution liquid. In particular, a person of ordinary skill in the art would understand that the oily or fatty base in the suppository would melt during the dissolution and would not dissolve in the phosphate buffer solution. A person of ordinary skill in the art would expect that this fat might cause a number of potential interfering effects such as clogging or obscuring the sample separation and measurement apparatus. Thus, in my opinion a person of ordinary skill in the art would find the "release" ambiguous.

53. In sum, my opinion is that a person of ordinary skill in the art would find the entire term "the suppository releases … mesalamine …of dissolution as measured with USP Apparatus #2 at 40° C., a paddle rotation speed of 125 rpm, and 3 sinker turns in 0.2 M phosphate buffer at a pH of 7.5" to be ambiguous.

E. "About" In Drug Load Terms

54. In my opinion, the constructions proposed in the Aptalis Disclosures for those claim terms concerning the drug load of the claimed inventions of the Asserted patents are improper, because they serve to exacerbate existing ambiguity within these terms.

55. I understand that the term "drug load" is defined for purposes of the *Aptalis v. Sandoz* action[2] to mean "the weight percentage of mesalamine based on the total weight of the suppository." I understand that Aptalis and Sandoz[3] have proposed the competing constructions listed in the table below:

Claim Terms	Aptalis's Proposed Construction	Sandoz's Proposed Construction
"drug load"	The parties have agreed to the following construction: "The weight percentage of mesalamine based on the total weight of the suppository."	
"the drug load ranges from about 39 to about 45%"	"[The mesalamine suppository … wherein] the drug load ranges from approximately 39% to approximately 45%"	"The weight percentage of the mesalamine in the suppository is no less than 38.5% and no greater than 45.4%, based on the total weight of the suppository." Alternatively, under Aptalis's proposed construction, this term is indefinite.
"the drug load ranges from about 41 to about 43%"	"[The mesalamine suppository … wherein] the drug load ranges from approximately 41% to approximately 43%"	"The weight percentage of the mesalamine in the suppository is no less than 40.5% and no greater than 43.4%, based on the total weight of the suppository." Alternatively, under Aptalis's proposed construction, this term is indefinite.

56. In my opinion, a person of ordinary skill in the art would interpret "about" to avoid any overlap of the ranges. "From about 41 to about 43%" would overlap if "about" included ± 1%.

[2] I understand that the term "drug load" was not a disputed term in the *Aptalis v. Mylan* case.
[3] I understand that Mylan asserts that these claim terms are indefinite under the applicable patent law. I have not considered the applicable patent law in forming my opinion regarding the meaning of these claim terms.

Similarly, "from about 39%" would also overlap with "from about 41%" if "about" included ± 1%. In my opinion, to avoid any overlap, a person of ordinary skill in the art would use mathematical rounding to define the specific ranges as set forth in Sandoz's proposed constructions above. Rounding is a standard practice in the art to define numerical boundaries in testing.

57. In my opinion, Aptalis' construction of "about" does not provide clarity or boundary on the term and could result in the lack of distinction between the numerical values in the ranges. Under the proposed construction in the Aptalis Disclosure, a person of ordinary skill in the art would not be able to distinguish between a claim of a drug load of "about 39%" and a claim of a drug load of "about 41%", where the measured drug load was 40%. Thus, a person of ordinary skill in the art would not be able to determine which claims she may be infringing with a drug load of 40%.

58. For at least these reasons, the drug load constructions proposed in the Aptalis Disclosure would not provide sufficient instruction to one of ordinary skill in the art in how to reproduce the claimed invention or to avoid infringement.

I declare under penalty of perjury pursuant to the laws of the United States of America that the forgoing statements are true and correct.

Jonathan W. Steed

Dated: May 2, 2014